DETAILED ACTION

Status of Claims

1. In applicant's reply filed on 10/14/09, applicant amended claims 1 and 20. Claim 4 was cancelled. Claims 1-3 and 5-20 are pending and are under examination.

Response to Amendment

Prior art rejections

2. In light of applicant's amendments, the body of the 35 USC 103(a) rejection over Allen is modified. The Office has applied the same prior art references and rejections, as cited in the prior Office Action, filed on 5/20/09.

Claim Interpretation

3. As to the pending claim(s) below, which contain intended use terms, the Examiner will interpret these claims in light of the structural elements that are disclosed and not for their intended use as stated after the term "for." The term, "for," is an intended use term. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

The Examiner has applied references, which are capable of meeting these functions. A structure, which is capable of providing the intended use, is considered to meet the limitation of intended use recited in a claim to a device or an apparatus.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. **Claims 1-3, 9-10, and 12-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. ("Allen," US 5837546, previously cited).

Regarding claim 1, Allen discloses a sample testing device for testing for the presence of a component of interest in a liquid sample, the device comprising:

at least one test capillary layer which has an upstream end and a downstream end and which incorporates an agglutination reagent system capable of causing agglutination with said component to be detected (i.e. col. 10, line 60 to col. 11, line 65; Allen reads on the language recited after "capable of" because such language is intended use language. Furthermore, with regard to the "system," the language describing such limitation, "agglutination reagent" appears to be a recitation of functional language. Allen's system is capable of performing the function recited with this term.);

a sampling region to which the liquid sample is applied and from which the sample is able to enter the upstream ends of the test capillary(s) (i.e. col. 12, lines 49-col. 13, line 2);

a power source (i.e. col. 8, line 1 to col. 10, line 26; col. 15, lines 28-59);

a detection arrangement electrically associated with said power source for detecting the presence of liquid at a downstream region of said testing capillary (i.e. col. 8, line 20 to col. 10, line 59; col. 14, line 54 to col. 15, line 59);

display means operated by said power source for indication the result of the test (the claim limitation, “display means,” does not invoke 35 USC 112, sixth paragraph because it does not use the phrase, “means for” or "step for” and such limitation appears to be modified by sufficient structure for achieving the specified function; i.e. col. 7, line 32 to col. 10, line 51*)*; and

signal processing means for determining whether the liquid sample reaches the detection arrangement within a pre-determined time period (the claim limitation, “signal processing means,” invokes 35 USC 112, sixth paragraph because the limitation satisfies the three prong test, see MPEP 2181; Allen anticipates the means-plus-function limitation because Allen, like applicant’s invention, discloses an equivalent signal processing means, which is a custom integrated circuit, see col. 9, lines 50-65; Allen reads on the language recited after, "wherein," because such language is a recitation with respect to the manner in which a claimed apparatus is intended to be employed).

Furthermore, with regard to claims 1 and 17 (see infra), while Allen discloses that his assay device can have many configurations including square, rectangle, triangle, oval, round or any other desired shape in col. 7, lines 54-67 and col. 11, lines 10-49, Allen does not specifically disclose that his test capillary is in the form of a capillary tube. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Allen's test capillary by specifically having one in the form of a capillary tube because Allen discloses that his assay device can be in the form of different shapes and that it would be desirable to have a particular shape, such as a

tube shape, that can be cost effectively contained with acceptable performance (i.e. Allen, col. 7, lines 54-67).

Regarding claim 2, the modified Allen discloses that the power source comprises electrodes of dissimilar metals provided at the sampling region of the device, said electrodes being adapted to generate a current when liquid sample is applied to said region (i.e. col. 15, lines 28-52; Allen reads on the language recited after, “adapted to,” because such language is intended use language).

Regarding claim 3, the modified Allen discloses that the electrodes of the dissimilar metals alternate with each other (i.e. col. 15, lines 28-52).

Regarding claim 9, the modified Allen reads on the claim language recited after, "capable of" because such language is intended use language.

Regarding claim 10, the claim appears to be a recitation of a product-by-process claim, which is of no patentable moment in an apparatus-type of claim.

Regarding claim 12, the modified Allen discloses that the detection arrangement comprises a pair of electrodes across which a potential difference may be applied (i.e. col. 15, line 28 to col. 17, line 35).

Regarding claims 13-15, the modified Allen discloses that his test capillary incorporates an inert particulate material (i.e. fiberglass is made of silica, col. 10, line 60 to col. 12, line 19).

Regarding claim 16, the modified Allen discloses that the particulate material is a swellable polymer (i.e. col. 10, line 60 to col. 11, line 20).

Regarding claim 17, the modified Allen discloses that at least one control capillary layer having an upstream end and a downstream end. Allen reads on the claim language recited after, "wherein" because such language is intended use language. (i.e. the other capillary test strip, see fig. 4).

Regarding claim 18, the claim language appears to be a recitation with respect to the manner in which a claimed apparatus is intended to be employed. The modified Allen reads on such claim language because the modified Allen discloses the structural features recited in this claim, i.e. control capillary and detection arrangement (see supra).

Regarding claim 19, the modified Allen discloses the his control capillary comprises a reagent system that is capable of being non-agglutinating (i.e. col. 5, line 45 to col. 7, line 25).

Regarding claim 20, the claim language appears to be a recitation with respect to the manner in which a claimed apparatus is intended to be employed. The modified Allen reads on such claim language because the modified Allen discloses the structural feature recited in this claim, i.e. timer (see supra).

6. **Claims 5-8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen in view of Wilding et al. ("Wilding," US 5486335, previously cited).

See Allen supra.

Regarding claims 5-8, while the modified Allen discloses a reagent system that comprises various binding members situated in the wall of the test capillary, such as an antibody, and is capable of causing agglutination, i.e. col. 5, line 45 to col. 7, line 30 and

col. 11, lines 10-65, the modified Allen does not specifically disclose a reagent system that comprises beads.

Wilding discloses in fig. 6, for example, that the binding moiety may comprise a particle capable of inducing detectable agglomeration of an analyte in the mesoscale flow system. As illustrated in device 10, shown schematically in FIG. 6, particles 42 coated with binding protein specific for a given analyte may be provided in the fractal region 40 to promote analyte-induced agglomeration of fluid in the fractal region. For example, a binding moiety such as an antibody may be immobilized on an inert bead, and may be utilized to induce agglomeration. Agglomeration in the fractal region may be detected optically through a window, e.g., disposed over the fractal region. Agglomeration may also be detected by, e.g., detecting pressure or conductivity changes of the sample fluid as noted below. (i.e. col. 9, line 66 to col. 10, line 41).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the modified Allen's reagent system by incorporating beads, as disclosed by Wilding, because it would be desirable to have a reagent system that can easily induce detectable agglomeration of an analyte (i.e. Wilding, col. 9, line 66 to col. 10, line 41).

7. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Allen in view of Forrow et al. ("Forrow," US 6764581, previously cited)

See Allen supra.

Regarding claim 11, while the modified Allen discloses downstream regions of the test capillary tube having at least one aperture and having a detection arrangement,

Allen does not specifically disclose that the detection arrangement is beneath the aperture.

Forrow discloses in FIGS. 1 and 2, an electrode support 1, typically made of PVC, polycarbonate, or polyester, supports three printed tracks of electrically conducting carbon ink 2. The printed tracks 2 define the positions of the working electrode 5, dummy electrode 5a, reference electrode 4, and electrical contacts 3. The contacts 3 fit into a compatible meter (not shown). The elongated portions of the printed tracks 2 of electrically conducting carbon ink are each overlaid with a silver/silver chloride particle track 6a, 6b, and 6c. Except for the electrode areas, the silver/silver chloride particle tracks 6a, 6b, 6c are overlaid with a layer of hydrophobic, electrically insulating material 7. The hydrophobic electrically insulating material is useful to surround the area containing the electrode arrangement. Hydrophobicity of the electrically insulating material is useful for confining the sample to the area containing the electrode arrangement. Two surfactant coated mesh layers 9, 10 overlay the electrodes 4, 5, 5a. The mesh layers protect the printed components from physical damage. They also facilitate wetting of the electrodes by the aqueous sample. Hydrophilicity of the mesh allows the sample to wick along the mesh layer to the electrodes. The upper mesh layer 10 helps to control the influx of sample as it travels from the sample application area toward the electrode arrangement. The upper mesh layer 10 does so by providing a space to accommodate air displaced by the sample. Spacing of the relatively large filaments in the upper mesh layer 10, perpendicular to the direction of sample flow, helps to control the sample flow by presenting repeated

physical barriers to the movement of the sample, as it travels along the sample transfer path. (i.e. col. 3, line 34 to col. 5, line 32).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the modified Allen's test capillary tube by specifically having his detection arrangement beneath an aperture in the downstream regions of the test capillary tube, as disclosed by Forrow, because it would be desirable to have an electrode sensor strip structural arrangement that improves the precision and accuracy of analyte measurements (i.e. Forrow, col. 2, lines 38-53).

Response to Arguments

8. Applicant's arguments filed 10/14/09 have been fully considered but they are not persuasive.

In response to applicant's argument that Allen does not teach or suggest a testing device including a means for determining whether or not a liquid samples reaches the detection arrangement within a pre-determined time period, the Office respectfully disagrees. Allen anticipates the means-plus-function limitation because Allen, like applicant's invention, discloses an equivalent signal processing means, which is a custom integrated circuit (i.e., see col. 9, lines 50-65 of Allen).

In response to applicant's argument that Allen employs a reagent strip and not a capillary tube, the Office respectfully does not find this argument to be convincing. The Office has addressed this claimed feature above, which states the following: while Allen discloses that his assay device can have many configurations including square, rectangle, triangle, oval, round or any other desired shape in col. 7, lines 54-67 and col.

11, lines 10-49, Allen does not specifically disclose that his test capillary is in the form of a capillary tube. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Allen's test capillary by specifically having one in the form of a capillary tube because Allen discloses that his assay device can be in the form of different shapes and that it would be desirable to have a particular shape, such as a tube shape, that can be cost effectively contained with acceptable performance (i.e. Allen, col. 7, lines 54-67).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LORE JARRETT whose telephone number is (571)272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LORE JARRETT/
Examiner, Art Unit 1797

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